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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bernard C.B. LIM, et al.
Title:	MEDICAL TREATMENT CONTROL SYSTEM
Appl. No.:	10/536,651
International Filing Date:	11/26/2003
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Examiner:	Unknown
Art Unit:	3736
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CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this correspondence is being electronically filed with the **United States Patent and Trademark Office**, on the date below.

Cindy Murphy
(Printed Name)

(Signature)

10-15-07
(Date of Deposit)

REQUEST FOR CORRECTED PUBLICATION UNDER 37 CFR §1.221(b)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby request correction of the publication of the above-captioned application in accordance with 37 C.F.R. §1.221(b). The application was published as publication number US 2007/0191787 on August 16, 2007, therefore, this request is timely filed.

The following Patent Office material mistakes appear in the publication:

At paragraph [0001], US provisional application 60/428,942 was filed on November 26, 2002, not 2007.

At paragraph [0154], please replace "RP ID" with --RF ID--.

Applicants submit that a Preliminary Amendment was filed along with the filing of the application indicating the insertion of the paragraph **[0001]**. As requested for correction, a copy of the relevant pages of the Preliminary Amendment are enclosed.

In support of this request, Applicants submit the relevant pages of the application as filed to indicate where in the specification is the relevant text and a marked-up copy of the relevant pages of the publication to show the requested corrections.

Applicants respectfully request corrected publication of the present application.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date 10/15/07

By V Bansal

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1139
Facsimile: (650) 856-3710

Vandana Bansal
Agent for Applicant
Registration No. 54,979

MEDICAL TREATMENT CONTROL SYSTEM

REFERENCE TO CO-PENDING APPLICATIONS

[0001] The entire subject matter of U.S. Provisional application Ser. No. 60/428,942 filed Nov. 26, 2007 and entitled BLOOD TREATMENT CONTROL SYSTEM is incorporated by reference. The applicant claims priority benefit under Title 35, United States Code, Section 119(e) of U.S. Provisional application Ser. No. 60/429,942 filed Nov. 26, 2002 and entitled BLOOD TREATMENT CONTROL SYSTEM.

[0002] The entire subject matter of U.S. Provisional application Ser. No. 60/464,659 filed Apr. 23, 2003 and entitled DISPENSING SYSTEMS is incorporated by reference. The applicant claims priority benefit under Title 35, United States Code, Section 119(e) of U.S. Provisional application Ser. No. 60/464,659 filed Apr. 23, 2003 and entitled DISPENSING SYSTEMS.

[0003] The entire subject matter of U.S. Provisional application Ser. No. 60/482,725 filed Jun. 27, 2003 and entitled MEDICAL TREATMENT CONTROL SYSTEM is incorporated by reference. The applicant claims priority benefit under Title 35, United States Code, Section 119(e) of U.S. Provisional application Ser. No. 60/482,725 filed Jun. 27, 2003 and entitled MEDICAL TREATMENT CONTROL SYSTEM.

BACKGROUND OF THE INVENTION

[0004] 1. Field of the Invention

[0005] The present invention relates to the controlling of medical treatments.

[0006] 2. Description of the Related Art

[0007] The field of medicine has worked diligently over the years to improve the safety of blood collection and delivery in patient care. The consequences of an error, for example in delivering a blood sample to the wrong patient, can be serious, if not severe. A current technique uses a series of four identically numbered decals that are used to track the two syringes, the disposable and the patient during the blood treatment. The blood treatment involves:

[0008] 1 Removing the blood from the patient to a syringe.

[0009] 2 Transporting that syringe to a blood treatment disposable within which the treatment occurs.

[0010] 3 Removing the treated blood from the disposable to the blood delivery syringe and

[0011] 4 Returning the blood to the patient

[0012] The serial number on the decals are compared to one another at each transfer step by the operator to ensure that the correct blood is tracked throughout the process to eventually ensure the correct blood is given to each patient.

[0013] At each comparison a decision is made and at each decision point there exists a potential for human error.

[0014] An intensive Care Unit (ICU) at a British hospital has gained recognition for its efforts to reduce errors in blood treatments. The system requires that a new patient entering a ward on the ICU receive a new wristband that contains the information of Date of Birth (DOB), Name, Hospital ID number and a 2D barcode that contains the same information as well as any allergies, blood type and medications that the patient is currently receiving. This information is also stored on the hospital database.

[0015] The ICU nurse can then order autologous or donated blood to be delivered to the ICU for the patient. The blood information is confirmed on the blood bank computer monitor and the correct blood is selected. New barcodes are printed and placed on those blood bags. The blood bags are delivered to the patient.

[0016] At the bedside, the blood bag barcode and patient barcode are scanned to see if the blood and patient match If they match, the operator or nurse is granted approval to proceed with the transfusion. If the match is not made, the nurse is not provided with approval and is given a warning not to transfuse the blood. The barcode reader and printed labels facilitates a machine assisted blood matching.

[0017] Despite the advances that have been made in the control of medical treatments, improvements are still needed.

SUMMARY OF THE INVENTION

[0018] In one of its aspects, the present invention provides a device for controlling the collection and delivery of blood, comprising a syringe-engaging portion, the syringe-engaging portion being operable in a release position to receive a syringe when the syringe is in a blood-containing configuration, the syringe-engaging portion being operable in a lock position for locking the syringe therewith, and access control means for controlling the release and lock positions according to a blood transaction condition.

[0019] In one embodiment, the syringe-engaging portion has a side wall containing a cavity to receive the syringe. The syringe is of the type having a body having a first end flange on one end thereof and a plunger slidably engaged with the body, the plunger having a second end flange on a remote end thereof the cavity having a first formation to receive the first end flange.

[0020] In one embodiment, the access control means further comprises at least one barrier portion to extend at least partially across the cavity in the lock position. In one example, the access control means has a pair of barrier members with opposing free end regions, the barrier members being movable between an open position wherein the free ends are separated to permit the syringe to pass therebetween and a closed position wherein the free ends are positioned sufficiently close to one another to prevent the removal or the addition of the syringe from the cavity. The barrier members are pivotally coupled to the syringe-engaging portion.

[0021] In one embodiment, the device has a control portion, the syringe-engaging portion being removably attached to the control portion. Actuating means are mounted in the control portion and are releasably coupled to the barrier members for actuating the barrier members between the open and closed positions. In addition, a second lock means is provided for locking the syringe engaging portion with the control portion, for reasons which will be described herein below.

S2 and transfers the treated blood sample identification data contained in the barcode to the syringe carrier **12** through the data transfer port of the docking bay **72**. Then, the syringe carrier is positioned so that the barcode reader can scan the treated sample identification on the second syringe **S2** to conform a match, at which point the barrier members **28** are released and the second syringe **S2** is transferred from the second station **54** in the platform **50** to the cavity and held therein by the barriers **28** in the lock position.

[0145] The syringe carrier **12** is then returned to the patient where the barcode reader is scanned over the wristband **38** to confirm a match between the treated blood sample and the subject patient. With the match established, the barrier members **28** may be transferred to their release position and the second syringe removed so that the treated blood may be delivered to the patient, to complete the process. At this point, the syringe engaging portion **20** may be released from the control portion **21** and the syringe engaging portion **20** discarded, along with the **S1**, **S2** syringes and the platform **50**. This ensures that all working parts of the system which are intimately associated with a blood sample can be disposed of while retaining other components of the system for re-use.

[0146] Thus, the data contained in the barcode and written or printed on the labels of the wristband **38** and the syringes are used to match and track the patient and the blood sample. The wristband contains the subject patient's name and Barcode ID. The syringe carrier **12** obtains and contains the barcode matching information as well as the written or printed patient name information thereon and the operator uses the barcode reader as a secondary matching device.

[0147] In addition, the syringe carrier **12** obtains data relating to the blood treatment which may merely record the time at which the blood treatment occurred. If desired, the syringe carrier **12** may also be configured to lock the syringe carrier, if a subsequent step in the blood treatment procedure has not been executed. For example, the syringe carrier may have a lock function triggered by the lack of a status signal received at each stage in the process. In this case, the syringe carrier may also be configured to release the lock after a predetermined access sequence is entered in the carrier, for example via the docking bay **72**.

[0148] Thus, in addition to the control of untreated and treated blood, samples, the syringe carrier may also accumulate audit trail data which may be uploaded to the blood treatment unit or some other intermediate device following a blood treatment procedure, wherein the audit trail data may be used to monitor the blood treatment to be sure that it was appropriate for the patient's particular condition. The audit trail data may, for instance, be analyzed over the course of a patients short term or long term treatment program, as needed.

The RF ID-Assisted Tracking with Name Label

[0149] In this example, the subject patient is fitted with a disposable RF ID scanner on his wrist, or elsewhere inside or outside his body, either attached with or spaced therefrom and the first and second syringes are equipped with RF ID chips within them, for example as shown schematically at **100**, **102**, **104** in FIG. **1**. If desired, written or printed name labels may be affixed on the wristband as well as the first and second syringes.

[0150] The treatment may proceed as before, except that the syringe carrier does not function to lock the first or second syringes in place. Rather, the verification function occurs between the wristband, the first syringe, the treatment unit and the second syringe.

[0151] The RF ID treatment procedure is proposed as follows. First, the wristband **38** and the first blood retrieval syringe **S1** are arranged so that each emits a common RF signal. The patient name and date of birth are written on the wristband as well as on the first and second syringes. A blood sample is then drawn from the patient using the first syringe and the wristband is attached to the wrist of the subject patient.

[0152] The syringe is delivered to the first station of the platform which is now in position in the treatment unit. At this point, the second delivery syringe is already installed in the second station of the platform. The treatment occurs where the treated blood sample is injected into the second delivery syringe. As shown by the dashed arrow at **106**, the treatment unit reads the RF ID on the first syringe and writes that ID onto the RF Tag of the second delivery syringe (as shown by the dashed arrow at **108**), as well as other data as described above such as a time stamp indicative of when the treatment occurred or other steps in the process as the case may be. This process of ID writing may only be done once, with current RF ID chips, though other devices may be available to make the writing process repeatable

[0153] The treatment is completed and the treatment unit opens to deliver a platform with an attached and empty first syringe and the attached second syringe containing the now treated blood sample. The second syringe is removed from the platform in the access port and is then transported to the patient. The patient is identified by name using the patient label on the second syringe.

[0154] The operator confirms the subject patient's identification by attempting to match RP ID data in the syringe with that contained in the patient's wristband by placing them in close proximity to one another. The wristband RF ID reader will emit a signal to confirm the match. The signal may be a sound or light emission, such as from a signal generator, an LED or the like.

[0155] The treated blood is then delivered to the patient. The wristband is removed from the patient and is taken to the treatment unit to close the audit trail and confirm that the treatment was completed.

The RF ID Assisted Tracking without Name Label

[0156] In this case, the RF ID based treatment procedure is as follows. First, a package is prepared containing a wristband, syringe carrier and first blood retrieval syringe. The wristband and the blood retrieval syringe have the same factory-installed and matching RF ID's. The patient's name and date of birth are written on the wristband and on a label provided on the syringe carrier.

[0157] The first syringe is used to draw a blood sample from the subject patient. The wristband is attached to the subject patient

[0158] The syringe carrier is used, as before, to deliver the blood to the first station on the platform which is carrying the second syringe in the second station and the platform is itself located in the blood sample receiving area in the access

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Art Unit: Not yet assigned

CERTIFICATE OF EXPRESS MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service's "Express Mail Post Office To Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

EV 576632831 US (Express Mail Label Number) May 26, 2005 (Date of Deposit)

Rene Campos (Printed Name)

(Signature)

PRELIMINARY AMENDMENT UNDER 37 CFR 1.115

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to examination of the present Application, Applicant respectfully requests that the application be amended as follows:

Amendments to the Specification are reflected on page 2 of this document.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this document.

Remarks/Arguments begin on page 14 of this document.

Please amend the application as follows:

Amendments to the Specification:

Please insert before the first paragraph of the application with the following:

--This application is a national phase application of PCT Application No. PCT/CA2003/001838, filed November 26, 2003, which claims the benefit under 35 U.S.C. § 119(e) of U.S. Patent Application No. 60/428,942, filed November 26, 2002; U.S. Patent Application No. 60/464,659, filed April 23, 2003; U.S. Patent Application No. 60/482,725, filed June 27, 2003 which are hereby incorporated by reference.--

The treatment is completed and the treatment unit opens to deliver a platform with an attached and empty first syringe and the attached second syringe containing the now treated blood sample. The second syringe is removed from the platform in the access port and is then transported to the patient. The patient is identified by name using the patient label on the second syringe.

The operator confirms the subject patient's identification by attempting to match RF ID data in the syringe with that contained in the patient's wristband by placing them in close proximity to one another. The wristband RF ID reader will emit a signal to confirm the match. The signal may be a sound or light emission, such as from a signal generator, an LED or the like.

The treated blood is then delivered to the patient. The wristband is removed from the patient and is taken to the treatment unit to close the audit trail and confirm that the treatment was completed.

THE RF ID ASSISTED TRACKING WITHOUT NAME LABEL

In this case, the RF ID based treatment procedure is as follows. First, a package is prepared containing a wristband, syringe carrier and first blood retrieval syringe. The wristband and the blood retrieval syringe have the same factory-installed and matching RF ID's. The patient's name and date of birth are written on the wristband and on a label provided on the syringe carrier.

The first syringe is used to draw a blood sample from the subject patient. The wristband is attached to the subject patient.

The syringe carrier is used, as before, to deliver the blood to the first station on the platform which is carrying the second syringe in the second station and the platform is itself located in the blood sample receiving area in the access port 48. The treatment unit is then activated to conduct a designated treatment on the blood sample. Thereafter, the treated blood is delivered to the second syringe.